Summary of the STAN® S 21 clinical database – data from the city of Gothenburg

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Background

The last century has seen dramatic developments in medical care as technological advances have been applied to both diagnosis and treatment. Some areas of obstetrics have been slow to benefit from these advances - and none more so than the care of the fetus in labour.
Fetal surveillance during labour constitutes a challenge in information management. To give birth is a natural process for women. For the child it may constitute a threat for intact survival and ominous changes may appear within minutes putting labour ward management to the forefront of medical high-risk management. The nurse/midwife/obstetrician manages this complex situation by visual analysis of a host of information constituting clinical, as well as directly recorded data from the fetus in particular. The current situation is far from satisfactory and a new strategy has to be developed and implemented to take obstetric management into the new century.

During the last five years the work has been intensified to develop and document the STAN concept of intrapartum fetal surveillance. The basis for this work has been the combination of experimental and clinical studies linked to the development of a new medical device, STAN® S 21. Recently, the results of the second RCT comparing standard electronic fetal heart rate monitoring (CTG) with CTG plus ST analysis of the fetal ECG were published. The current report summarizes the situation with regard to outcome measures such as cord metabolic acidosis, rate of operative indications for fetal distress and risk of moderate/severe neonatal encephalopathy after the introduction of the STAN concept in clinical practice. It includes data obtained from all deliveries that have occurred in the city of Gothenburg and surrounding area during a period of 16 months when the STAN concept of intrapartum fetal monitoring and obstetric management was introduce.

Methodology

The two maternity wards located at Sahlgrens Univ Hospital/Oestra and the district general hospital at Moelndal were equipped with 8 STAN® S 21 units in August – September 2000 after the educational process had been ongoing during the summer months. These are large labour ward units, each with >3500 deliveries per year. There are 236 midwifes and approx. 100 doctors involved in labour ward management. Each hospital had one part time midwife responsible for the education and data collection. Data from cases monitored with STAN have been collected using a specific case report. For those cases not monitored with STAN, the hospital-based database has been used. Clinical records at two neonatal units were reviewed for cases of newborn encephalopathy. Neonatal encephalopathy was defined as follows: minor, with irritability and jitteriness; moderate, with profound lethargy or abnormal tone; and severe, with coma or abnormal tone and seizures.

Cord blood acid-base assessment is part of routine care; cord artery and vein samples after double clamping of the cord, should be obtained from every delivery. Cord artery metabolic acidosis was defined as a pH <7.05 in combination with a base deficit in the extra-cellular fluid compartment (BD_{ecf}) >12.0 mmol/L, using the Siggaard-Andersen Acid Base Chart algorithm.

Results

During the period starting 1st October 2000 and finishing 31st January 2002, 10296 deliveries occurred with a gestational age > 36 completed weeks. Of all pregnancies at term, 2821 were monitored with STAN. Cord acid-base data was obtained in 83% of all term deliveries.
Table I provides the relative distribution of indications for use of the STAN monitor based on the first 700 cases monitored at Moelndal's hospital.

Table I. Indications to start a STAN recording	
Abnormal CTG pattern	16,6%
Meconium stained amniotic fluid	16,9%
Antenatal risk factors; postmaturity, IUGR, preeclampsia, diabetes	5,6%
External monitoring failure	3,0%
Vaginal bleedings	1,4%
Doctors orders	2,6%
Midwifes perceived need for further information, own choice	54,0%

Table II provides rates of cord artery metabolic acidosis in term pregnancies in active labour related to method of fetal surveillance in labour. Furthermore, cases with moderate/severe neonatal encephalopathy are also indicated. The table also includes data on the rate of operative deliveries for fetal distress in the group monitored with STAN.

Table II
Outcome data obtained during the first and the latest four months period of STAN usage in the city of Gothenburg.

Time period	Cord acid-base data, %	Cord artery Metabolic acidosis, %	Moderate/Severe Encephalopathy, no of cases and incidence	ODFD total %	ODFD CS%
Oct-00 - Jan-01, n=2261 pregnancies at term in active labour.					
Total	90.1	1.03	5, 2.2‰		
STAN monitoring, n= 668, 29.5% of all	92.4	0.97	2	14,4	7
Standard CTG monitoring, n=1593	89.1	1.06	3		
Oct-01 – Jan-02, n=2256 pregnancies at term in active labour.					
Total	86.5	0.26*	1 0.44‰		
STAN monitoring, n= 764, 33.9% of all	86.3	0.61	1	9.2*	4.1*
Standard CTG monitoring, n=1492	86.6	0.08**	0		

Met acidosis: pH<7.05 + BDecf >12 mmol/L. ODFD: operative deliveries for fetal distress, CS: caesarean sections, * p<0.05, ** p<0.01, paired Student's t-test

Table III provides detailed information on the six cases in the STAN group with moderate/ severe encephalopathy recorded during the 16 months period.

Table III. Clinical characteristics in cases monitored with STAN and developing neuromuscular symptoms, including increased neuromuscular tone, seizures and neonatal death, excluding lethal malformations, in relation to the occurrence and type of ST-events.

Case N.o* Date of delivery	Labour data			Neonate Postnatal course				
	ST event	Duration of ST-event	Mode of delivery	Apgar Score 1,5 and 10 min	pH	BDecf, mmol/L	Comments	Days in SCBU
MLA 260,	Baseline T/QRS	180 + 13 min	NVD	1-7-8	-	-	Normal pregnancy. 41 w. No cord data available. Neonatal seizures, small intracerebral bleeding.	5
OED 1161,	Baseline T/QRS	16 min	Mid-cavity VE, ODFD	3-6-8	7.15	5.5	Normal pregnancy. 40 w. Meconium aspiration. Post natal asphyxia, neonatal seizures, and signs of brain oedema. Normal at 10 months follow-up.	9
OED 204,	Biphasic ST+ Baseline T/QRS	2h 17 min + 12 min	NVD	6-7-9	6.95	11.4	Normal pregnancy. 37 weeks gestation. Neonatal seizures, subarachnoidal bleeding, normal EEG. Listeria septicaemia, normal at 5 months follow-up.	13
OEA 1215,	Baseline T/QRS	35 min	Pelvic outlet VE, ODFD	2-7-8	6.97	15.3	Normal pregnancy, 39 w. Maternal pyrexia. E-coli septicaemia, early neonatal death	2h
MLA 675,	Biphasic ST + Baseline T/QRS	3h 30 min + 1h 20 min	NVD	3-5-5	6.97	18.0	Normal pregnancy, 41w. Meconium aspiration, neonatal seizures at 12h of age, multi organ symptoms, abnormal EEG.	20
MLB 828,	Baseline T/QRS	4 min	NVD	3-5-8	7.30	0	Normal pregnancy, neonatal seizures at 12h of age, normal neuroimaging (CT) and EEG.	11

VE: ventouse; CS: caesarean section; ODFD: operative delivery for fetal distress; NVD: normal vaginal delivery: EEG: electroencephalogram: CT: computed tomography of the brain.

During the same period, eight cases monitored with standard CTG technology have developed signs of moderate/severe encephalopathy. Out of these three died. They were all post term and were delivered by emergency caesarean sections for fetal distress. Of the remaining five, two had postnatal causes (pulmonary atelectasis and

infection) and three had cord acidosis (pH 6.7 – 7.03). Since the latest case of moderate/severe encephalopathy, 2001 term deliveries have been monitored during active labour with standard CTG technology. None of these neonates have shown neurological symptoms.

Discussion

Recently, the outcome of the Swedish multi center randomized controlled trial was presented, showing significant reductions of cases of cord metabolic acidosis at the same time as the rate of ODFD was decreased. However, it can always be argued that a clinical trial provides special focus on the issues studied. Thus, it should be of interest to further document the introduction of a new technology as was done with the current follow-up in busy maternity wards with a large number of caregivers. This possibility has been provided to us by the maternity units purchasing STAN equipment to establish ST analysis as part of the clinical guidelines of intrapartum care. The data illustrate changes in perinatal outcome during a 16 months period with the introduction of the STAN technology of intrapartum fetal monitoring together with dedicated training, case discussions and enhanced user experience.

The Swedish RCT showed the most marked improvements when the STAN technology was used adequately and with increasing experience. This was also the finding in the current study, not only among those cases monitored with ST analysis but also in the group of more normal deliveries monitored with standard CTG technology.
It is of interest to notice that the STAN concept, which not only includes ST analysis but also provide a focus on more consistent CTG analysis has been improving outcome with regard to metabolic acidosis not only in the CTG+ST group but also in the group of cases monitored with CTG only. Currently 33.7% of term deliveries in active labour are monitored with STAN and with a limited number of monitors available at each labour ward unit, it seems likely that these are cases where there is a need for further information on the condition of the fetus.

The data show that automatic ST analysis of the fetal ECG provided a significant improvement in obstetric care with regard to the rate of cord artery metabolic acidosis and reduction in operative deliveries for fetal distress. This is an effect built on local experience and confidence in the technology developed over time.

The outcome after one year of STAN usage indicates that both the rates of low cord artery metabolic rates (0.57%) and ODFD (total: 5.9%, CS: 1.93%) seen in the CTG+ST arm of the Swedish RCT when the STAN technology was used adequately, may be achieved during standard practice conditions as well.

The primary aim of intrapartum fetal surveillance is to reduce the risk of long-term sequele caused by adverse events during labour. Among the six cases of moderate/ severe encephalopathy monitored with the STAN technology, two had normal acid-base data at delivery indicating a postnatal cause. These cases had ST events of < 20 minutes duration. Of the remaining four, two had neonatal findings of bacterial infections (E-coli and Listeria monocytogenes) that would be an additional factor responsible for an adverse outcome. In one case the baby showed short lasting

seizures in association with a small cerebral bleeding and no other neonatal symptoms. In only one case, there were signs of long lasting intrapartum hypoxia with marked metabolic acidosis, multi organ symptoms and ST events of > 1h duration, for further information, see enclosed case report.

The data indicate that application of the STAN concept to alter labour ward management in a relatively short time frame substantially reduces the risk of newborns being affected by adverse events in labour. This has not previously been shown.

Thus we may summarise accordingly:

ST analysis of the fetal ECG during labour has been documented to improve neonatal outcome. The mechanisms behind this development seem to be more accurate knowledge of how to record, assess and respond to specific ST changes. This has been achieved through the following mechanisms:

A. Access to educational material that is well accepted both by doctors and midwifes.

B. Adequate monitoring technology and a user confidence in the information provided by ST analysis.

C. A clinically useful marker that is of sufficient specificity and prevalence to inform about intrapartum hypoxia before the baby is at risk. Umbilical cord metabolic acidosis serves this purpose well. Cases of metabolic acidosis still occur. However, it appears as if there is an improved margin of safety when ST analysis is added to electronic fetal monitoring, as cases of intrapartum hypoxia potentially serious enough to cause neonatal brain injury are not missed.

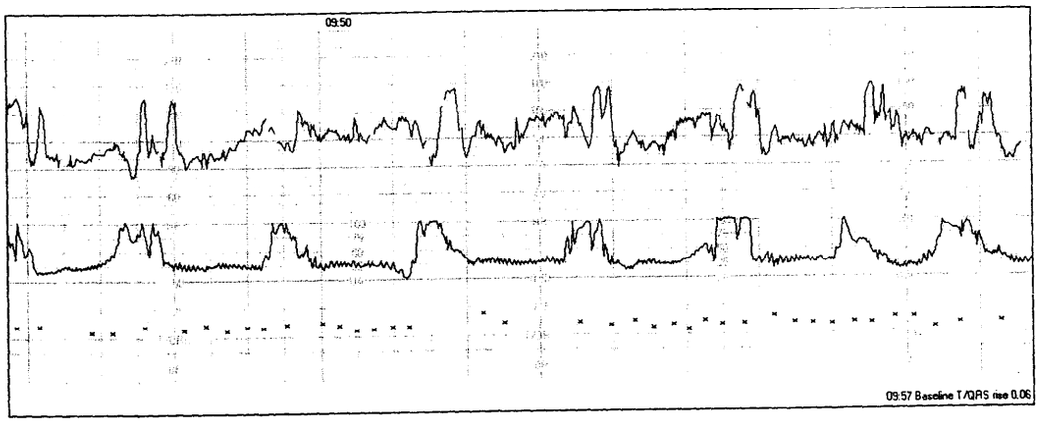
D. When such cases occur, there is the possibility of providing immediate user feedback comparing the individual case data to the CTG+ST guidelines.

Case report MLA 675

~~~-old para 0, normal pregnancy, spontaneous onset of labour after 41 gestational weeks. Oxytocin infusion, Epidural. Meconium stained amniotic fluid. Normal admission test.
Onset active pushing at 10:00.
NVD at 11:19
Male, 3770g, Apgar 3-5-5
Cord vein pH 6.97, PCO2 6.69 kPa, BDecf 18.0 mmol/l
Assisted ventilation + suctioning of airways –meconium. Spontaneous breathing at 10 min of age but develops signs of pulmonary maladaptation with accumulating PCO_2. On respirator at 1 hr of age. Signs of persistent fetal circulation with meconium aspiration. Hypotension with lowest mean arterial pressure of 30 mmHg. Treated with sympathomimetic drugs. Develops seizures at 12 hrs of age, verified on the EEG. On respirator for 4 days. From day 2, signs of gradual improvement. Normal behaviour and neurological findings at discharge on day 19.

Assessment of recording

STAN S 21 recording of good quality commencing ~~~ at 17:07 and finishing next day at 11:17, i.e. 2 minutes before delivery.
Normal CTG pattern until onset of active pushing at 10:00. At this point in time increased basal FHR of 170 bpm in association with episodes of increased variability and some complicated decelerations are noted.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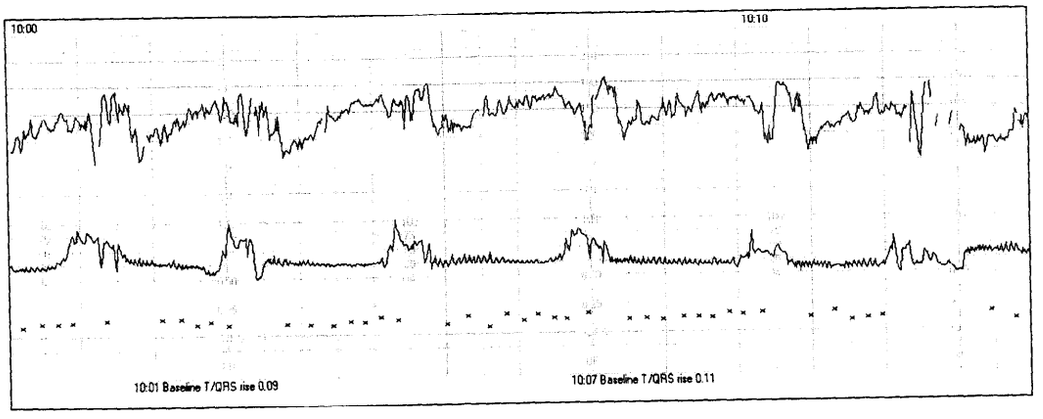
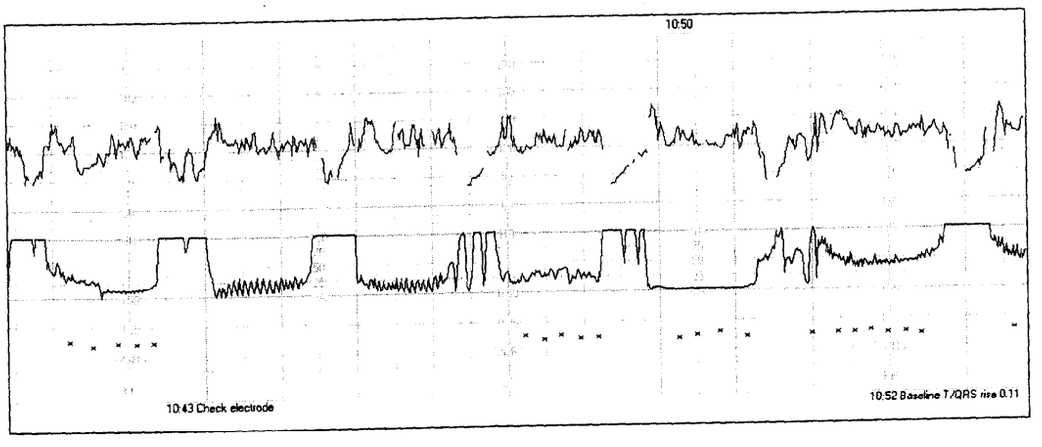
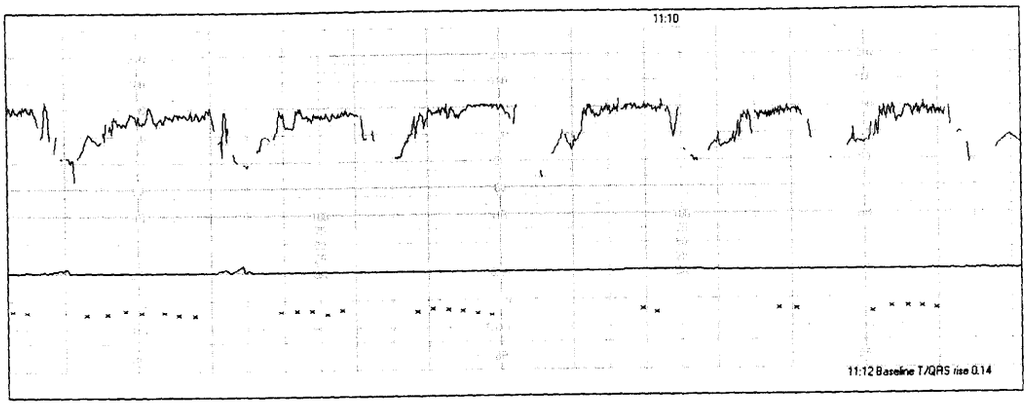


After approx 30 minutes, the baseline FHR returns to normal before it starts to rise slowly from 140 to 155 bpm. The decelerations changes their pattern to become short lasting and rather uniform and early. Heart rate variability appears normal throughout this period.
The ST log has identified a series of ST events, starting with the appearance of biphasic ST changes from 07:50 until 09:17 when a baseline rise is noted in association with the occurrence of short lasting but marked decelerations and an increase in variability. Five contractions per 10 minutes during this late phase of 1st stage.



With onset of active pushing a second baseline TQRS rise is noted. This rise continues until delivery with the following ST log statements;
09:57 – 0.06
10:01 – 0.09
10:07 – 0.11
10:52 – 0.11
11:12 – 0.14

Final part of the recording, normal vaginal delivery at 11:19.



Comments

This is a case of normal pregnancy that develops signs of hypoxia during labour with marked metabolic acidosis in the cord vein, low Apgar and need for resuscitation, multi organ symptoms and severe encephalopathy. Significant ST events starting with the appearance of biphasic waveforms 3.5 hrs before delivery and a marked ST rise with onset of active pushing commencing 1h 20 min before delivery. Obviously, the CTG pattern was assessed to be normal due to the maintained heart rate variability and lack of consistent marked decelerations. However, on retrospective analysis, FHR changes did occur in association with the rise in TQRS with onset of active pushing. The rise in baseline TQRS exceeding 0.10 indicated a need for acute delivery even if the CTG would only have been assessed as intermediary.

The case reinforces previous findings of acute hypoxia in 2nd stage being best reflected by the rise in TQRS. It also shows how a fetus may increase its heart rate variability pattern with the hypoxic alarm reaction. This pattern corresponds to that seen experimentally during the initial phase of hypoxia. Under these circumstances a decrease in fetal heart rate variability may be a late sign of fetal compromise.